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*Apotex Inc. and Apotex Corp.*

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

THE MEDICINES COMPANY,

Plaintiff,

v.

APOTEX INC. and APOTEX CORP.,

Defendants

Civil Action No. 3:13-cv-02801-PGS-DEA

***DOCUMENT ELECTRONICALLY FILED***

**ANSWER OF APOTEX INC. AND APOTEX CORP. TO COMPLAINT  
FOR PATENT INFRINGEMENT, ADDITIONAL DEFENSES,  
AND COUNTERCLAIMS**

Defendants Apotex Inc. and Apotex Corp. (“Defendants” or “Apotex”), by its undersigned counsel, Cozen O’Connor, for its Answer to the Complaint filed by The Medicines Company (“Plaintiff”), states as follows:

**GENERAL DENIAL**

Pursuant to Fed. R. Civ. P. 8(b)(3), Apotex denies all allegations in The Medicine Company’s Complaint except those specifically admitted below.

**NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 7,582,727 (“the ’727 patent”) (attached as Exhibit A) and 7,598,343 (“the ’343 patent”) (attached as Exhibit B).

**ANSWER:** Apotex admits that Plaintiff purports to bring this action under 35 U.S.C. § 271 *et seq.* for infringement of United States Patent Nos. 7,582,727 (“the ’727 patent”) and 7,598,343 (“the ’343 patent”). All other allegations are denied.

**THE PARTIES**

2. Plaintiff The Medicines Company is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 8 Sylvan Way, Parsippany, New Jersey 07054.

**ANSWER:** Upon information and belief, Apotex admits that Plaintiff is a corporation with a place of business at 8 Sylvan Way, Parsippany, New Jersey 07054. Apotex lacks knowledge or information sufficient to form a belief as to the truth of all remaining allegations of Paragraph 2, and on that basis denies these allegations.

3. Upon information and belief, defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, with a principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

**ANSWER:** Apotex admits that Apotex Inc. is a corporation organized and existing under the laws of Canada and has a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

4. Upon information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

**ANSWER:** Apotex admits that Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

5. Upon information and belief, Apotex Corp. is an agent, affiliate, or subsidiary of Apotex Inc., including for Abbreviated New Drug Application (“ANDA”) No. 204876 (“Apotex’s ANDA”).

**ANSWER:** Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Apotex Corp. is designated as Apotex Inc.’s agent on ANDA No. 204876.

### **JURISDICTION AND VENUE**

6. This Court has jurisdiction over the subject matter of this action under 28U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that subject matter jurisdiction exists only for any claims asserted under 35 U.S.C. § 271(e)(2). Apotex denies all remaining allegations of Paragraph 6.

7. This Court has personal jurisdiction over Apotex.

**ANSWER:** Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only.

8. Upon information and belief, Apotex has a continuous and systematic business presence within this judicial district and/or substantial events giving rise to acts of infringement have occurred and/or will occur within this judicial district, including but not limited to: (i) the preparation of and/or contribution to the submission and/or filing of ANDA No. 204876 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (codified at 21 U.S.C. § 355(j)) seeking approval to market a 250 mg/vial bivalirudin drug product for intravenous injection (“Apotex’s Product”) before the expiration of the ’727 and ’343 patents; and/or (ii) making, using, selling, offering for sale, and/or importing Apotex’s Product.

**ANSWER:** Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex states that ANDA No. 204876 speaks for itself. Apotex further states that solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 8.

9. Apotex has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by filing suit in this jurisdiction and/or by asserting counterclaims in other civil actions initiated in this jurisdiction. (*See, e.g., Otsuka Pharmaceutical Co., Ltd. v. Apotex Corp. et al.*, Civil Action No. 12-05645 (D.N.J.) (ECF No. 27); *Meda Pharmaceuticals Inc. v. Apotex Inc., et al.*, Civil Action No. 12-00361 (D.N.J.) (ECF No. 25); *Novartis Pharmaceuticals Corp. v. Apotex Inc. et al.*, Civil Action No. 12-05574 (D.N.J.) (ECF No. 12)).

**ANSWER:** Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties

and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only.

10. Upon information and belief, Apotex's business includes developing, manufacturing, distributing, and/or selling generic drug products for sale and use throughout the United States, including for sale and use within this judicial district.

**ANSWER:** Apotex admits that their business includes developing and manufacturing pharmaceuticals, including quality generic medicines. Apotex denies all remaining allegations of Paragraph 10.

11. Upon information and belief, Apotex has derived revenue from generic drug products distributed and/or sold in the State of New Jersey.

**ANSWER:** Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it has distributed and/or sold generic pharmaceutical products in the State of New Jersey. Apotex denies all remaining allegations of Paragraph 11.

12. Upon information and belief, Apotex has registered with the New Jersey Department of Health and Senior Services as: (i) a business or firm engaging in the wholesale distribution of drugs under N.J.A.C. 8:21 Subchapter 3A and/or; (ii) a drug manufacturing business or a wholesale nonprescription drug business under N.J.S.A. 24:6B-1.

**ANSWER:** Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Apotex Corp. is registered with the New Jersey Department of Health and Senior Services. Apotex denies all remaining allegations of Paragraph 12

13. Upon information and belief, Apotex's "Registration Number" with the New Jersey Department of Health and Senior Services is 5003192.

**ANSWER:** Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that New Jersey Department of Health and Senior Services has issued Apotex Corp. registration number 5003192. Apotex denies all remaining allegations of Paragraph 13.

14. Upon information and belief, Apotex has and continues to avail itself of the laws of the State of New Jersey, including but not limited to N.J.A.C. 8:21 Subchapter 3A and/or N.J.S.A. 24:6B-1.

**ANSWER:** Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only.

15. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and § 1400(b).

**ANSWER:** Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction or venue in this Judicial District solely for the limited purposes of this action only.

16. Upon information and belief, (i) Apotex operates a permanent business location within this judicial district and can, therefore, be found in this judicial district and is a resident of this judicial district; and/or (ii) substantial events giving rise to acts of infringement have occurred and/or will occur within this judicial district, including in connection with Apotex's preparation of and/or contribution to the submission and/or filing of ANDA No. 204876 under §505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to market Apotex's Product before the expiration of the '727 and '343 patents.

**ANSWER:** Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that subject matter jurisdiction

exists only for any claims asserted under 35 U.S.C. § 271(e)(2). Apotex denies all remaining allegations of Paragraph 16.

**FACTS AS TO ALL COUNTS**

17. The Medicines Company is the owner of New Drug Application (“NDA”) N020873, which was approved by the FDA for the manufacture and sale of Angiomax®. Angiomax® is the trade name for bivalirudin, 250 mg/vial, for intravenous injection, which is indicated, among other things, for use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty.

**ANSWER:** Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that the electronic version of the FDA publication, Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the “*Orange Book*”), identifies NDA No. N020873 for Angiomax® as being bivalirudin, 250 mg/vial, for intravenous injection, and lists “The Medicines Company” as the approval holder for NDA No. N020873. Defendants lack knowledge or information sufficient to form a belief as to the truth of all remaining allegations of Paragraph 17, and on that basis, denies all remaining allegations.

18. The ’727 patent, entitled “Pharmaceutical formulations of bivalirudin and processes of making the same,” was duly and legally issued on September 1, 2009, to The Medicines Company upon assignment from Gopal Krishna and Gary Musso. The ’727 patent is generally directed to bivalirudin compositions.

**ANSWER:** Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that, according to the electronic records of the United States Patent and Trademark Office (“Patent Office”), the Patent Office issued the ’727 patent, entitled “Pharmaceutical formulations of bivalirudin and processes of making the same,” on or about September 1, 2009. According to the electronic records of the

Patent Office, The Medicines Company is a purported assignee of the '727 patent. Apotex denies all remaining allegations of Paragraph 18.

19. The '343 patent, entitled "Pharmaceutical formulations of bivalirudin and processes of making the same," was duly and legally issued on October 6, 2009, to The Medicines Company upon assignment from Gopal Krishna and Gary Musso. The '343 patent is generally directed to bivalirudin compositions.

**ANSWER:** Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that, according to the electronic records of the United States Patent and Trademark Office ("Patent Office"), the Patent Office issued the '343 patent, entitled "Pharmaceutical formulations of bivalirudin and processes of making the same," on or about October 6, 2009. According to the electronic records of the Patent Office, The Medicines Company is a purported assignee of the '343 patent. Apotex denies all remaining allegations of Paragraph 19.

20. In accordance with 21 U.S.C. § 355(b)(1), the '727 and '343 patents are listed in FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering The Medicines Company's Angiomax® product.

**ANSWER:** Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that the '727 and '343 patents are listed in FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") in connection with The Medicines Company's Angiomax® product. Apotex denies all remaining allegations of Paragraph 20.

21. Upon information and belief, Apotex filed its ANDA with the FDA under § 505(j) of the FDCA seeking approval to engage in the manufacture, use, sale, offer for sale, and/or importation of Apotex's Product before the expiration of the '727 and '343 patents.



**ANSWER:** The contents of Defendants' ANDA No. 204876 speak for itself. Apotex denies the remaining allegations of Paragraph 21.

22. Upon information and belief, Apotex Inc. sent The Medicines Company a letter purporting to include a notice of certification for the '727 and '343 patents under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. 505(j)(2)(B)(ii) of the FDCA regarding Apotex's Product ("Apotex's Notice Letter").

**ANSWER:** Apotex admits they notified Plaintiff by letter that Defendants had submitted ANDA No. 204876 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355 (j)). The content of Defendants' Notice Letter speaks for itself. Apotex denies all remaining allegations of Paragraph 22.

23. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21C.F.R. §§ 314.95(c)(6)(i)-(ii).

**ANSWER:** Paragraph 23 contains legal conclusions and allegations to which no answer is required.

24. Apotex's Notice Letter did not contain a detailed statement or include the factual and legal basis for asserting that Apotex's Product does not infringe each claim of the '727 and '343 patents.

**ANSWER:** Apotex denies the allegations of Paragraph 24.

### **FIRST COUNT**

(Infringement of the '727 Patent by Apotex – ANDA No. 204876)

25. The Medicines Company repeats and incorporates by reference each paragraph above.

**ANSWER:** Paragraph 25 contains legal conclusions and allegations to which no answer is required. Defendants incorporate their answers to Paragraphs 1 to 24 as if fully set forth herein.

26. Upon information and belief, Apotex seeks FDA-approval for the manufacture, use, sale, offer for sale, and/or importation of Apotex's Product that is the subject of ANDA No. 204876.

**ANSWER:** The contents of Defendants' ANDA speak for itself. To the extent that an answer may be required, Apotex admits that it seeks approval of its ANDA No. 204876.

27. Upon information and belief, Apotex's ANDA includes a paragraph IV certification to the '727 patent to obtain approval to engage in the manufacture, use, sale, offer for sale, and/or importation of Apotex's Product before the expiration of the '727 patent.

**ANSWER:** Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that obtaining final FDA approval of ANDA No. 204876 will permit Apotex to promote, sell, and/or distribute its proposed bivalirudin, 250 mg/vial, drug product for intravenous injection in the United States. Apotex denies all remaining allegations of Paragraph 27.

28. Upon information and belief, Apotex will manufacture, sell, offer for sale, and/or import Apotex's Product upon FDA-approval, including within this judicial district.

**ANSWER:** Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent than an answer may be required, Apotex filed ANDA No. 204876 with the FDA seeking approval to market the bivalirudin, 250 mg/vial for injection product. Apotex further states that Apotex lacks knowledge or information sufficient to form a belief as to the truth of all allegations of Paragraph 28, as Paragraph 28 is speculative, and on that basis, Apotex denies the remaining allegations of Paragraph 28.

29. Upon information and belief, as of the date of Apotex's Notice Letter for Apotex's ANDA, Apotex was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

**ANSWER:** Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex is aware of statutory provisions in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6). Apotex denies all remaining allegations of Paragraph 29.

30. The inclusion of a paragraph IV certification to the '727 patent in Apotex's ANDA for the purpose of obtaining approval to engage in the manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Product before the expiration of the '727 patent is an act of infringement by Apotex of one or more claims of the '727 patent directly and/or indirectly in a cooperative venture under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent that an answer may be required, Apotex denies the allegations of Paragraph 30.

31. Upon information and belief, Apotex's manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Product will infringe one or more claims of the '727 patent directly under 35 U.S.C. § 271(a) and/or indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

**ANSWER:** Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent that an answer may be required, Apotex denies the allegations of Paragraph 31.

32. Apotex admits that Apotex's Product infringes the '727 patent because, among other things, Apotex's Notice Letter does not provide a basis - let alone a detailed factual and legal basis - for noninfringement of each claim of the '727 patent. Specifically, Apotex's Notice Letter does not provide a detailed factual and legal basis for noninfringement of claims 1-10 and 17 of the '727 patent.

**ANSWER:** Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent that an answer may be required, Apotex denies the allegations of Paragraph 32.

33. Upon information and belief, Apotex is aware of the existence of the '727 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '727 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

**ANSWER:** Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent that an answer may be required, Apotex admits they are aware of the existence of the '727 patent. Apotex denies all remaining allegations of Paragraph 33.

34. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless Apotex is preliminarily and permanently enjoined by this Court.

**ANSWER:** Apotex denies the allegations of Paragraph 34.

### **SECOND COUNT**

(Infringement of the '343 Patent by Apotex – ANDA No. 204876)

35. The Medicines Company repeats and incorporates by reference each paragraph above.

**ANSWER:** Paragraph 35 contains legal conclusions and allegations to which no answer is required. Defendants incorporate their answers to Paragraphs 1 to 34 as if fully set forth herein.

36. Upon information and belief, Apotex seeks FDA-approval for the manufacture, use, sale, offer for sale, and/or importation of Apotex's Product that is the subject of ANDA No.204876.

**ANSWER:** The contents of Defendants' ANDA speak for itself. To the extent that an answer may be required, Apotex admits that it seeks approval of its ANDA No. 204876.

37. Upon information and belief, Apotex's ANDA includes a paragraph IV certification to the '343 patent to obtain approval to engage in the manufacture, use, sale, offer for sale, and/or importation of Apotex's Product before the expiration of the '343 patent.

**ANSWER:** Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that obtaining final FDA approval of ANDA No. 204876 will permit Apotex to promote, sell, and/or distribute its proposed bivalirudin, 250 mg/vial, for intravenous injection product in the United States. Apotex denies all remaining allegations of Paragraph 37.

38. Upon information and belief, Apotex will manufacture, sell, offer for sale, and/or import Apotex's Product upon FDA-approval, including within this judicial district.

**ANSWER:** Paragraph 38 contains legal conclusions and allegations to which no answer is required. To the extent than an answer may be required, Apotex lacks knowledge or information sufficient to form a belief as to the truth of all allegations of Paragraph 38, as Paragraph 38 is speculative as to a future event, and on that basis, Apotex denies the allegations of Paragraph 38.

39. Upon information and belief, as of the date of Apotex's Notice Letter for Apotex's ANDA, Apotex was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

**ANSWER:** Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex is aware of statutory provisions in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6). Apotex denies all remaining allegations of Paragraph 39.

40. The inclusion of a paragraph IV certification to the '343 patent in Apotex's ANDA for the purpose of obtaining approval to engage in the manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Product before the expiration of the '343 patent is an act of infringement by Apotex of one or more claims of the '343 patent directly and/or indirectly in a cooperative venture under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent that an answer may be required, Apotex denies the allegations of Paragraph 40.

41. Upon information and belief, Apotex's manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Product will infringe one or more claims of the '343 patent directly under 35 U.S.C. § 271(a) and/or indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

**ANSWER:** Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent that an answer may be required, Apotex denies the allegations of Paragraph 41.

42. Apotex admits that Apotex's Product infringes the '343 patent because, among other things, Apotex's Notice Letter does not provide a basis - let alone a detailed factual and legal basis - for noninfringement of each claim of the '343 patent. Specifically, Apotex's Notice Letter does not provide a detailed factual and legal basis for noninfringement of claims 1-11 of the '343 patent.

**ANSWER:** Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent that an answer may be required, Apotex denies the allegations of Paragraph 42.

43. Upon information and belief, Apotex is aware of the existence of the '343 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '343 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

**ANSWER:** Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent that an answer may be required, Apotex admits they are aware of the existence of the '343 patent. Apotex denies all remaining of Paragraph 43.

44. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless Apotex is preliminarily and permanently enjoined by this Court.

**ANSWER:** Apotex denies the allegations of Paragraph 44.

**PRAYER FOR RELIEF**

Apotex denies that Plaintiff is entitled to any of the relief requested in its Prayer for Relief.

**APOTEX'S ADDITIONAL DEFENSES**

Apotex asserts the following defenses without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted.

**FIRST AFFIRMATIVE DEFENSE**

Plaintiff's Complaint fails to state a claim upon which relief may be granted

**SECOND AFFIRMATIVE DEFENSE**  
**(INVALIDITY)**

The '727 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**THIRD AFFIRMATIVE DEFENSE**  
**(NO DIRECT INFRINGEMENT)**

Apotex does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '727 patent and Apotex's products that are the subject of ANDA No. 204292 do not infringe any valid and enforceable claim of the '727 patent.

**FOURTH AFFIRMATIVE DEFENSE**  
**(NO INDIRECT INFRINGEMENT)**

Apotex has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '727 patent, and the marketing, sale, and/or distribution of Apotex's products that are the subject of ANDA No. 204292 does not induce the

infringement of, or contribute to the infringement of any valid and enforceable claim of the '727 patent.

**FIFTH AFFIRMATIVE DEFENSE**  
**(INVALIDITY)**

The '343 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**SIXTH AFFIRMATIVE DEFENSE**  
**(NO DIRECT INFRINGEMENT)**

Apotex does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '343 patent and Apotex's products that are the subject of ANDA No. 204292 do not infringe any valid and enforceable claim of the '343 patent.

**SEVENTH AFFIRMATIVE DEFENSE**  
**(NO INDIRECT INFRINGEMENT)**

Apotex has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '343 patent, and the marketing, sale, and/or distribution of Apotex's products that are the subject of ANDA No. 204292 does not induce the infringement of, or contribute to the infringement of any valid and enforceable claim of the '343 patent.

**EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

**NINTH AFFIRMATIVE DEFENSE**

Plaintiff fails to state a proper claim for willful infringement or exceptional case.



**TENTH AFFIRMATIVE DEFENSE**

The Complaint fails to state a cause of action under 35 U.S.C. §§ 271(a)-(c) against Apotex because Plaintiff has not plead with particularity facts regarding any post- ANDA-approval activities.

**ELEVENTH AFFIRMATIVE DEFENSE**

Any additional defenses or counterclaims that discovery may reveal.

### **APOTEX'S COUNTERCLAIMS**

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Apotex, Inc. and Apotex Corp. (collectively, "Apotex"), by way of its attorneys Cozen O'Connor, hereby state for their Counterclaims against The Medicines Company ("Counterclaim Defendant"), the following:

1. Apotex repeats and incorporates by reference each of the foregoing paragraphs of Apotex's Answer and Separate Defenses to the Complaint.
2. This is an action for a declaratory judgment of non-infringement and invalidity, of one or more claims of United States Patent Nos. 7,582,727 ("the '727 patent") and 7,598,343 ("the '343 patent") under 28 U.S.C. §§ 2201 and 2202. Upon information and belief, a true and correct copy of the '727 patent was attached to the complaint (D.I. 1) as Exhibit A, and a true and correct copy of the '343 was attached to the complaint (D.I. 1) as Exhibit B.

### **THE PARTIES**

3. Apotex, Inc. is corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.
4. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce parkway, Suite 400, Weston Florida, 33326.
5. On information and belief, Counterclaim Defendant The Medicines Company is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 8 Sylvan Way, Parsippany, New Jersey 07054.

### **JURISDICTION**

6. This court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Apotex, on the one hand, and Counterclaim Defendant The Medicines Company, on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*
7. This court has personal jurisdiction over Counterclaim Defendant The Medicines Company based, *inter alia*, on the filing by Counterclaim Defendant The Medicines Company of this lawsuit in this jurisdiction and because Counterclaim Defendant The Medicines Company is doing business in this jurisdiction.
8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

### **ORANGE BOOK LISTING OF THE ‘727 AND ‘343 PATENTS**

9. On information and belief, on September 1, 2009, the United States patent and Trademark Office (“USPTO”) issued United States Patent No. 7,582,727 (“the ‘727 patent”), entitled Pharmaceutical formulations of bivalirudin and processes of making the same. According to the electronic records of the USPTO, The Medicines Company, is the purported assignee of the ‘727 patent.
10. On information and belief, on October 6, 2009, the United States patent and Trademark Office (“USPTO”) issued United States Patent No. 7,598,343 (“the ‘343 patent”), entitled Pharmaceutical formulations of bivalirudin and processes of making the same. According to the electronic records of the USPTO, The Medicines Company, is the purported assignee of the ‘343 patent.

11. The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act require NDA holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holder believes claim the “drug” for which their NDA is submitted, or patents covering a “method of using such drug.” 21 U.S.C. §§ 355(b)(1) and (c)(2).
12. On information and belief, pursuant to 21 U.S.C. §§ 355(b)(1)(G), Counterclaim Defendant The Medicines Company caused the FDA to list the ‘727 and the ‘343 patents in the Orange Book in connection with NDA No. 020873 for ANGIOMAX® (bivalirudin), 250 mg/vial, for injection (“the ANGIOMAX® NDA”).
13. By maintaining the listings of the ‘727 and ‘343 patents in the Orange Book, Counterclaim Defendant The Medicines Company represent that the ‘727 and the ‘343 patents “could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1)(G).

#### **APOTEX’S ABBREVIATED NEW DRUG APPLICATION**

14. Apotex filed ANDA No. 204876 with the FDA seeking approval to market the bivalirudin, 250 mg/vial, for injection described therein.

#### **THE PRESENCE OF A CASE OR CONTROVERSY**

15. By maintaining the orange Book listing of the ‘727 and ‘343 patents in connection with the ANGIOMAX® NDA, Counterclaim Defendant The Medicines Company continues to represent that the ‘727 and ‘343 patents could reasonably be asserted against anyone making, using or selling generic bivalirudin, 250 mg/vial, for injection without a license from The Medicines Company.

16. Counterclaim Defendant The Medicines Company has filed an infringement action under 35 U.S.C. § 271(e)(2)(A) and 35 U.S.C. §§ 271(a), (b), and (c) asserting the ‘727 and ‘343 patents against Apotex Inc. and Apotex Corp. There has been and is now an actual and justiciable controversy between Apotex Inc. and Apotex Corp. on the one hand and Counterclaim Defendants The Medicine Company on the other hand as to whether the products disclosed in Apotex’s ANDA No. 204876 infringe the ‘727 and/or the ‘343 patents and whether any valid, enforceable claim in either the ‘727 or ‘343 patents exist.
17. Apotex seeks to market the bivalirudin, 250 mg/vial, for injection product that is the subject of ANDA No. 204875 in the United States.
18. If Apotex succeeds in proving that its bivalirudin, 250 mg/vial, for injection product does not infringe the ‘727 or ‘343 patents or that the ‘727 or ‘343 patents are invalid or unenforceable, such a judgment will remove any uncertainty that may exist by virtue of Counterclaim Defendant The Medicine Company’s maintenance of the ‘727 and ‘343 patents in the Orange Book in connection with the ANGIOMAX® NDA.
19. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaim Defendant The Medicines company and Apotex as to whether the claims of the ‘727 and ‘343 patents are invalid and/or not infringed by Apotex.

**FIRST COUNT**

**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT  
OF THE '727 PATENT)**

20. Apotex repeats and incorporates by reference each of the foregoing paragraphs of Apotex's Answer and Separate Defenses to the Complaint and of these Counterclaims.
21. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Apotex and Counterclaim Defendant The Medicines Company concerning the claims of the '727 patent.
22. Counterclaim Defendant The Medicines Company asserts that the commercial manufacture, use, offer for sale, or sale of the Apotex's bivalirudin, 250 mg/vial, for injection product described in ANDA No. 204876 infringe the claims of the '727 patent.
23. Apotex asserts that no valid claim of the '727 patent is infringed by the manufacture, use, offer for sale, or sale of Apotex's bivalirudin, 250 mg/vial, for injection product described in ANDA No. 204876.
24. Apotex is entitled to a declaration that the manufacture, use, offer for sale, and sale of Apotex's bivalirudin, 250 mg/vial, for injection product described in ANDA No. 204876 do not infringe any valid claim of the '727 patent.

**SECOND COUNT**

**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '727 PATENT)**

25. Apotex repeats and incorporates by reference each of the foregoing paragraphs of Apotex's Answer and Separate Defenses to the Complaint and of these Counterclaims.
26. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Apotex and Counterclaim Defendant The Medicines Company concerning the claims of the '727 patent.
27. Counterclaim Defendant The Medicines Company asserts that the commercial manufacture, use, offer for sale, or sale of the Apotex's bivalirudin, 250 mg/vial, for injection product described in ANDA No. 204876 infringe the claims of the '727 patent.
28. Apotex asserts that the manufacture, use, offer for sale, or sale of Apotex's bivalirudin, 250 mg/vial, for injection product described in ANDA No. 204876 does not infringe any valid claim of the '727 patent, and that the claims of the '727 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation.
29. Apotex is entitled to a declaration that the claims of the '727 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation.

**THIRD COUNT**

**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT  
OF THE '343 PATENT)**

30. Apotex repeats and incorporates by reference each of the foregoing paragraphs of Apotex's Answer and Separate Defenses to the Complaint and of these Counterclaims.
31. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Apotex and Counterclaim Defendant The Medicines Company concerning the claims of the '343 patent.
32. Counterclaim Defendant The Medicines Company asserts that the commercial manufacture, use, offer for sale, or sale of the Apotex's bivalirudin, 250 mg/vial, for injection product described in ANDA No. 204876 infringe the claims of the '343 patent.
33. Apotex asserts that no valid claim of the '343 patent is infringed by the manufacture, use, offer for sale, or sale of Apotex's bivalirudin, 250 mg/vial, for injection product described in ANDA No. 204876.
34. Apotex is entitled to a declaration that the manufacture, use, offer for sale, and sale of Apotex's bivalirudin, 250 mg/vial, for injection product described in ANDA No. 204876 do not infringe any valid claim of the '343 patent.



**FOURTH COUNT**

**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '343 PATENT)**

35. Apotex repeats and incorporates by reference each of the foregoing paragraphs of Apotex's Answer and Separate Defenses to the Complaint and of these Counterclaims.
36. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Apotex and Counterclaim Defendant The Medicines Company concerning the claims of the '343 patent.
37. Counterclaim Defendant The Medicines Company asserts that the commercial manufacture, use, offer for sale, or sale of the Apotex's bivalirudin, 250 mg/vial, for injection product described in ANDA No. 204876 infringe the claims of the '343 patent.
38. Apotex asserts that the manufacture, use, offer for sale, or sale of Apotex's bivalirudin, 250 mg/vial, for injection product described in ANDA No. 204876 does not infringe any valid claim of the '343 patent, and that the claims of the '343 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation.
39. Apotex is entitled to a declaration that the claims of the '343 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation.

**PRAYER FOR RELIEF**

WHEREFORE, Defendants Apotex Inc. and Apotex Corp. respectfully request that the Court enter a judgment and Order in their favor and against Plaintiff and Counterclaim Defendant The Medicines Company as follows:

- A. For a declaration that the claims of U.S. Patent Nos. 7,582,727 and/or 7,598,343 are invalid;
- B. For a declaration that the claims of U.S. Patent Nos. 7,582,727 and/or 7,598,343 are not and will not be infringed by Apotex Inc. and Apotex Corp.;
- C. Preliminarily and permanently enjoin Plaintiff, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiff, from utilizing U.S. Patent Nos. 7,582,727 and/or 7,598,343 to block, hamper, hinder or obstruct FDA approval of Defendants' proposed products;
- D. Permanently enjoin Plaintiff, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiff, from asserting or otherwise seeking to enforce U.S. Patent Nos. 7,582,727 and/or 7,598,343 against Defendants or anyone in privity with Defendants;
- E. Granting Apotex Inc. and Apotex Corp. judgment in their favor on Plaintiff's Complaint;
- F. Denying any request by Plaintiff for injunctive relief;
- G. Dismissing Plaintiff's Complaint with prejudice;
- H. For an award of attorneys' fees pursuant to 35 U.S.C. § 285, other status or rules, or the general power of the Court;
- I. For an award of costs; and
- J. Awarding any other such relief as is just and proper.

Dated: July 19, 2013

s/ Andrew P. Nemiroff  
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*Apotex Inc. and Apotex Corp.*

**CERTIFICATE OF SERVICE**

I hereby certify that on this 19<sup>th</sup> day of July, 2013, a copy of the Defendant's **ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT, ADDITIONAL DEFENSES, AND COUNTERCLAIMS** was electronically filed and copies were served by ECF upon all counsel of record in this matter

Dated: July 19, 2013

s/ Andrew P. Nemiroff